GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1345
ANSWERED ON:18.07.2014
CLINICAL TRIALS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of applications received and approved by the Central Drugs Standard Control Organization (CDSCO) for conducting clinical trials on human beings in the country during each of the last three years and the current year;

(b) the details of the cases of irregularities, malpractices and violation of guidelines reported and the action taken/ proposed to be taken by the Government thereon during the said period;

(c) the number of clinical trial related injuries and deaths reported and the compensation paid in each of these cases indicating the criteria/method adopted for the purpose during the said period;

(d) the number of complaints for non-payment of compensation received along with the action taken/proposed to be taken by the Government thereon during the said period; and

(e) the corrective steps being taken by the Government to strengthen regulatory and monitoring mechanism for proper conduct of clinical trials and to ensure safety/protection of rights of trial participants in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

(a): The number of clinical trial related applications received and number of permissions granted by CDSCO during last three years and current year is as under:

Year	No. of Application Received	No. of Permission Granted
2011	306	283
2012	480	253
2013	207	73
2014 (till 30th June 2014)	104	95

(b): A statement containing the details of irregularities reported during the last three years and the current year and the action taken by the CDSCO is laid on the table of the House.

(c) & (d): As per the available information:

i) The number of clinical trial related Serious Adverse Events (SAEs) of injuries reported during the year 2011 and 2012 were 140 and 112, respectively.

ii) The number of clinical trial related Serious Adverse Events (SAEs) of deaths reported during each of the year 2011 and 2012 were 16.

iii) So far, orders for payment of compensation have been issued to the clinical trial applicants/sponsors in 19 cases of clinical trial related deaths in 2013 and in 8 out of these 19 cases, the respective Clinical Trial Applicants / Sponsors have already paid the compensation.

iv) Consequent to the amendments made in the Drugs and Cosmetics Rules, 1945 vide Gazette Notification G.S.R. 53 (E) dated 30.1.2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines, a formula has been prepared by the Expert Committee constituted under the Appendix XII of Schedule Y of the Rules to determine the quantum of compensation in cases of clinical trial related deaths. The quantum of compensation in such cases is being determined according to the said formula.

v) No complaints for the non-payment of the compensation have been received.

(e): The following measures have been taken by the Government to strengthen the approval procedure for clinical trials, monitoring mechanism and to ensure that safety, rights and well-being of clinical trial subjects are protected:

Amendment in the Drugs & Cosmetics Rules vide Gazette Notification G.S.R. 53 (E) dated 30.1.2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

Amendment in the Rules vide Gazette Notification G.S.R. 63(E) dated 1.2.2013 specifying various conditions for conduct of clinical trials, mandatory registration of clinical trial in clinical trial registry of India, authority for conducting clinical trial inspections and actions in case of non-compliance.

Amendment in the Rules vide Gazette Notification G.S.R. 72(E) dated 8.2.2013 specifying requirements and guidelines for registration of Ethics Committees.

An Expert Committee has been constituted to examine the reports of deaths in clinical trials. The committee has prepared a formula for determining the quantum of compensation in case of clinical trial related deaths which is available in CDSCO website.

In compliance to the Hon'ble Supreme Court's order dated 3.1.2013 in the case of Swasthya Adhikar Manch, Indore Vs Union of India & others, a system of supervision of clinical trial has been put in place by constituting a Technical Committee under Chairmanship of DGHS and an Apex Committee under Chairmanship of Secretary, Health and Family Welfare.

Order dated 30.8.2013 has been issued by CDSCO making it mandatory for the sponsor or his representatives to furnish the details of the contract entered by the Sponsor with the Investigator/Institutions with regard to financial support, fees, honorarium, payments in kind etc., to be paid to the Investigator.

In light of the order of Hon'ble Supreme Court dated 21.10.2013, it has been made mandatory with effect from 30.11.2013 that in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, is required to be done.

The committee set up under the Chairmanship of Prof. Ranjit Roy Chaudhury on clinical trial and new drugs has submitted its report. The Ministry of Health & Family Welfare examined the recommendations and pursuant to the same, orders were issued by CDSCO on 3.7.2014 for various measures to strengthen the regulation of clinical trials.